US Serial No. 10/645248 Page 6 of 17

Remarks:

Regarding the submission of claims 37 and 45

In this paper the applicant has amended the status indicator of these two claims to indicate that they are "withdrawn-previously presented" from prosecution. The applicant nonetheless hopes that these two method claims may be reinstated if rewritten to include other limitations of allowable composition claims at an appropriate time.

Regarding the rejection of claims 30-36, and 38-44 under 35 USC 102(e) or 35 USC 103(a) in view of US 6080387 to Zhou, et al. (hereinafter "Zhou"):

The applicant's present amendments to the independent claims are believed to render the prior rejection of the claims as moot.

With regard to Zhou, the applicant yet again points out that Zhou's compositions necessarily comprise the following constituents (see Zhou, col. 3):

The aerozol formulation comprises an antimicrobial composition that is mixed with a propellant. The composition has the following ingredients:

- (a) an anionic polymer or prepolymer;
- (b) a quaternary ammonium compound, the components
 (a) and (b) combining to form an antimicrobially effective complex;
- (c) at least one water-soluble or dispersible organic solvant having a vapor pressure of at least 0.001 mm Hg at 25° C., said at least one organic solvent present in a solvantizing—or dispersion—effective amount;

25

- (d) an effective amount of a propellant; and
- (c) the remainder, water.

Additional adjuncts in small amounts such as buffers, fragrances, dyes and the like can be included to provide desirable attributes of such adjuncts.

Therein is clearly indicated that amongst essential constituents are (a) and (b) which "... the components combining to form an antimicrobially effective complex.." This is further supported by Zhou in his statement at column 4 wherein he indicates that:

US Serial No. 10/645248 Page 7 of 17

The antimicrobial composition is preferably prepared by mixing effective amounts of the anionic component and the quaternary ammonium compound in water with agitation. A water miscible solvent and/or dispersing/emulsifying/ westing agent is preferably added before the two main

As well as at column 5 where he indicates that:

part of the invention. The most preferred range of 5:1 to 1:5 appears to result in an aesthetically pleasing film which has 15 excellent residual antimicrobial efficacy, as well as disinfectancy. This also seems to imply that, in the cured film/residue, there may actually not be complete ion pairing between the quaternary ammonium compound and the anionic sites in the anionic polymer, since the quaternary 20 ammonium active sites are available for residual microbial kill, although there is clearly an interaction between the two components. Again, the mechanism of the film/residue is not

And later at column 5 Zhou unequivocally "critically" identifies the role of the quaternary ammonium compound, or surfactant as being the <u>sole</u> agent responsible for providing a bacteriostatic/disinfectant benefit wherein he recites:

A critical second component of the invention is a quaternary ammonium compound, or surfactant. These types of 40 surfactants are typically used in bathroom cleaners because they are generally considered "broad spectrum" antimicrobial compounds, having efficacy against both gram positive (e.g., Staphylococcus sp.) and gram negative (e.g., Escherichia coli or Klebsiella sp.) microorganisms. Thus, the quaternary ammonium surfactant, or compounds, are incorporated for bacteriostatic/disinfectant purposes and should be present in amounts effective for such purposes.

From the foregoing, it is made <u>unequivocally clear</u> that Zhou's compositions require this "(a)+(b) complex" in order to provide an antimicrobial benefit, and particularly in view of the foregoing passages of Zhou, that the quaternary ammonium compound provides the antimicrobial benefit. Thus it is clear to see that the both (a) and (b), (..but especially the quaternary ammonium compound...) are (i) essential constituents, and (ii) the quaternary ammonium compound provides the antimicrobial benefit. Thus the (a)+(b)

US Serial No. 10/645248 Page 8 of 17

complex define the operative mechanism for providing an antimicrobial benefit according to Zhou.

Zhou's compositions then <u>do not</u> anticipate the applicant's presently presented claims, which outline a different "system" of constituents which provide a specific (and high) degree of antimicrobial efficacy, as is recited in part of claims 30 and 38, namely:

"...A hard surface treatment composition effective in providing Poliovirus (Type I) reduction consisting of:

ethanol in an amount of from about 45- 70%wt.;

0.01 – 5%wt. of a pH adjusting agent such that the pH range of the composition is from about 7.0 to about 13.0;

and water:

and further, optionally, one or more constituents selected from the group consisting of: corrosion inhibitors, perfumes, perfume carriers, deodorants, organic solvents, surfactants other than quaternary ammonium compounds which act as germicides, propellants, pH buffers, organic acids, fungicides, filmforming polymers and anti-oxidants; ..."

This feature is not known, nor demonstrated, nor would be obvious from the Zhou reference. Neither of applicant's independent claims 30 or 38 require Zhou's compositions comprising his "(a)+(b) complex". Applicant's claimed compositions, in their various claimed forms, do not require Zhou's "(a)+(b) complex", as is clearly evident from even a simple review of the present applicant's specification, applicant's claimed compositions do not require either (a) or (b), nor the "(a)+(b) complex" in order to provide an antimicrobial benefit. Further, in this paper, the applicant has also excluded "quaternary ammonium compounds which act as germicides" as an optional constituent, thus Zhou's (b) constituent is excluded and thus, his necessary (a)+(b) complex could not arise. Thus, prima facie, applicant's invention which provides effective antimicrobial efficacy absent the "(a)+(b) complex" is a clear indication that a different operative mechanism is at work, and thus is prima facie both unanticipated and nonobvious over the Zhou reference. The Examiner's assertions to the contrary are unsupported by the

US Serial No. 10/645248 Page 9 of 17

Zhou reference for the reasons outlined above. The Examiner is further reminded that "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994) Additionally, a reference may teach away from a use when that use would render the result inoperable. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). Thus, it is unequivocally clear that Zhou's "(a)+(b) complex" are a fundamental and necessary feature of Zhou's compositions. To follow the Examiner's line of reasoning in eliminating Zhou's necessary "(b)" constituent, would effectually render Zhou's compositions, which rely upon his "(a)+(b) complex" as being inoperable.

In the alternative, at best, the Examiner's selective reading of Zhou appears to be an impermissible "hindsight reconstruction" of the applicant's claimed invention. The Examiner is reminded that in *In re Fritch*, 972 F.2d 1260, 1266, 23 USPQ2d 1780, 1784 (Fed. Cir. 1992), the Federal Circuit stated:

"It is impermissible to use the claimed invention as an instruction manual or "template" to piece together the teachings of the prior art so that the claimed invention is rendered obvious. *In re Gorman*, 933 F.2d 982, 987, 18 USPQ2d 1885, 1888 (Fed. Cir. 1991). This court has previously stated that "[o]ne cannot use hindsight reconstruction to pick and choose among isolated disclosures in the prior art to deprecate the claimed invention." (quoting *In re Fine*, 837 F.2d at 1075, 5 USPQ2d at 1600)

See also W.L. Gore & Associates, Inc. v. Garlock, Inc. 220 USPQ 303 (CAFC, 1983); In re Mercier 185 USPQ 774, 778 (CCPA, 1975); In re Geiger 2 USPQ2d 1276 (CAFC, 1987).

Applicant's claimed system of aqueous-alcohol mixture within a specific pH range is not demonstrated providing a specific reduction of the Polio virus is not anticipated, nor even remotely suggested by Zhou's very different system which necessarily comprises Zhou's

US Serial No. 10/645248 Page 10 of 17

two essential constituents, namely his "a) anionic polymer or prepolymer" and b) quaternary ammonium surfactant, both of which are necessary to form Zhou's polymer complex which is used to provide his antipathogenic benefits. Further, as it is also clear that the applicant's invention and it success in the eradication of undesirable pathogens and fungi are based on a system of constituents which are distinguishable from Zhou's "(a)+(b)" combination, applicant's currently claimed compositions should also be considered nonobvious thereover, particularly in view of the amended claims presented in this paper which now expressly exclude a "film-forming polymer" as an available optional constituent. Without such a material, a key feature of Zhou's compositions are expressly absent and Zhou is properly overcome.

Accordingly, in view of the foregoing remarks, reconsideration of the propriety of the rejection under 35 USC 102(e) and/or 35 USC 103(a) is requested, and withdrawal of the rejection is urged.

Regarding the rejection of claims 30-36 under 35 USC 102(b) and/or 35 USC 103(a) in view of US 3282776 to Kitzke (hereinafter simply "Kitzke"):

The applicant traverses the Examiner's rejection of the indicated claims in view of Kitzke, particularly in view of the amended claims presented in this paper.

A review of Kitzke teaches the reader that the component of Kitzke's composition which provides disinfection is the necessary "Quaternary" compounds. Kitzke recites at col. 7:

US Serial No. 10/645248 Page 11 of 17

(d) Quaternary.—Although a vast array of germicides are available commercially today including numerous quaternary compounds the compositions of the invention are limited to a specific class of quaternary compounds described in detail below. These compounds are unexpectedly well suited for use in the surface disinfectingair sanitizing compositions of the invention by reason of their preeminent bactericidal properties. These quaternaries have been found to provide unobvious and unexpected surface disinfecting and air sanitizing performance when used in the compositions of the invention.

THE HOLL O AMMICHANIA ORDINA OR MAY MANUAL

These quaternary compounds comprise a mixture of two classes of compounds. The first class of compounds 20 can be represented structurally as:

wherein R_1 represents a mixture of n-alkyl groups comprising a major amount of C_{14} a lesser amount of C_{18} and minor amounts of C_{12} and C_{18} alkyl groups. The foregoing shall be referred to hereinafter as Formula II.

The second class of quaternary compounds can be repre- 35 sented structurally as:

wherein R_2 represents a mixture of n-alkyl groups comprising a major amount of C_{12} lesser amounts of C_{14} and C_{16} and a minor amount of C_{18} alkyl groups. The foregoing shall be referred to hereinafter as Formula III. These Formula II and III compounds can be described broadly as n-alkyl dimethyl benzyl ammonium chlorides and n-alkyl dimethyl ethylbenzyl ammonium chlorides respectively.

US Serial No. 10/645248 Page 12 of 17

The need for the quaternary surfactants are reinforced by a review of the results reported on Kitzke's "Table 1" and "Table 3" each of which clearly identify the need for a pair of quaternary ammonium compounds needed to provide a disinfecting benefit to Kitzke's aerosol compositions. Thus, from the foregoing it is clear that Kitzke neither "anticipates" the applicant's currently claimed compositions, or that applicant's currently claimed compositions could be considered "obvious" from the Kitzke reference and especially the compositions taught therein. Kitzke unequivocally teaches his pair of quaternary ammonium compounds as an essential constituent in order to provide a disinfecting benefit, the current applicant's teach a different system which provides as surprisingly effective benefit in controlling unwanted microorganisms. The applicant makes reference to the amended parts of claims 30 and 38, which in relevant part read:

"...A hard surface treatment composition effective in providing Poliovirus (Type I) reduction consisting of:

ethanol in an amount of from about 45-70%wt.;

0.01 – 5%wt. of a pH adjusting agent such that the pH range of the composition is from about 7.0 to about 13.0;

and water:

and further, optionally, one or more constituents selected from the group consisting of: corrosion inhibitors, perfumes, perfume carriers, deodorants, organic solvents, surfactants other than quaternary ammonium compounds which act as germicides, propellants, pH buffers, organic acids, fungicides, film-forming polymers and anti-oxidants; ..."

The applicant notes that the amended claim is believed to be equally relevant to the current rejection in view of Kitzke, as well as having been relevant to the prior rejection in view of Zhou, and similarly the amended claims are believed to now overcome the Examiner's rejection of the Kitzke reference as well. Accordingly, reconsideration of the propriety of the rejection under 35 USC 102(e) and/or 35 USC 103(a) is requested, and withdrawal of the rejection is urged.

US Serial No. 10/645248 Page 13 of 17

Regarding the prior rejection of claims 38-44 under 35 USC 103(a) in view of US 4695453 to Tuominen, et al. (hereinaster "Tuominen"), in view of US 6080387 to Zhou et al. ("Zhou") or in view of US 3282776 to Kitzke ("Kitzke"):

As the applicant traverses the current grounds of rejection of the indicated claims in view of the primary reference of Tuominen, when considered with the secondary references of Zhou or Kiztke.

Tuominen is solely directed to thickened alcohol containing compositions, as summarized by Tuominen at col. 3 which reads:

SUMMARY OF THE INVENTION

This invention relates to alcoholic antibacterial compositions containing a thickening amount of a polymer having the recurring structural unit:

wherein R is a divalent hydrocarbon group and M is a hydrogen atom or an ammonium group. This invention also relates to methods of thickening an alcoholic antibacterial composition and to the use of the thickened alcoholic antibacterial composition as an antibacterial agent.

The above recited polymer combined with an "Alcoholic Antibacterial Composition (AAC)" which comprises a major proportion of C_1 - C_8 aliphatic alkanols as well as aromatic substituted alkanols, e.g., benzyl alcohol. (Tuominen, col. 2, lines 4 – 14) but preferably the aqueous-alcohol comprises:

15 The preferred alcoholic antibacterial compositions preferably contain as active ingredients, a major portion (e.g. between about 40% and about 50% by weight) ethanol (wherein the ethanol contains 4% water), a minor portion (e.g. between about 20% and 30% by 20 weight) anhydrous isopropanol, and a nominal amount (e.g. about 0.5% to about 2% by weight) benzyl alcohol.

US Serial No. 10/645248 Page 14 of 17

As noted at col. 2 of Tuominen. Water forms, at best, only a minor amount of the (AAC), as can be understood from the following excerpt from col. 4:

Alcoholic Antibacterial Composition (AAC): A mixture comprised of approximately 46% by weight ethanol (which contains about 4% water and has been denatured), 27% anhydrous isopropanol, 1% benzyl alcohol and balance water, which is available from Henkel KGaA as Spitacid ®.

Thus, from the foregoing it is understood that the polymeric thickener of Tuominen is an <u>essential constituent</u> in all of his compositions. Tuominen fails to indicate the pH of his compositions, and very importantly fails to indicate or demonstrate any efficacy of his compositions against any specific miroorganisms.

For the sake of brevity, applicants herein repeat and incorporate by reference the prior remarks made with respect to Zhou as being equally applicable to the current rejection in conjunction with Tuominen. However, the additional consideration of Zhou with Tuominen would not be technically feasible and would be considered inoperable as Tuominen's thickened AAC compositions would be recognized by a skilled artisan as being unsuitable for use in a pressurized, propellant containing composition which is an essential feature of Zhou's compositions as such would be expected to clog any nozzle or dispenser due to the high viscosity of Tuominen's thickened AAC compositions. Such an inoperative combination would not render the applicant's presently claimed invention as being anticipated or being obvious and does not provide a suitable basis for maintaining the rejection of the claim. A reference may teach away from a use when that use would render the result inoperable. McGinley v. Franklin Sports, Inc., 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." In re Gurley, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994).

US Serial No. 10/645248 Page 15 of 17

In addition to the above, the additional consideration of Zhou also would require that the Tuominen thickened AAC composition would also necessarily require a germicidally effective quaternary ammonium compound, which is an essential constituent in Zhou's "(a)+(b)" complex. The currently amended independent claims exclude germicidally effective quaternary ammonium compound as possible, albeit optional, constituents.

Accordingly, reconsideration of and withdrawal of the rejection of the claims in view of the combined Tuominen and Zhou references is solicited.

For the sake of brevity, applicants herein repeat and incorporate by reference the prior remarks made with respect to Kitzke as being equally applicable to the current rejection in conjunction with Tuominen. As noted immediately above, Tuominen teaches a thickened AAC composition based on a specific thickening polymer as necessary constituents. Kitzke teaches aerosol compositions which provides disinfection due to the presence of specific quaternary compounds. That such are essential constituents is seen from Kitzke who recites at col. 7:

(d) Quaternary.—Although a vast array of germicides are available commercially today including numerous quaternary compounds the compositions of the invention are limited to a specific class of quaternary compounds described in detail below. These compounds are unexpectedly well suited for use in the surface disinfectingair sanitizing compositions of the invention by reason of their preeminent bactericidal properties. These quaternaries have been found to provide unobvious and unexpected surface disinfecting and air sanitizing performance when used in the compositions of the invention.

The need for the quaternary surfactants are reinforced by a review of the results reported on Kitzke's "Table 1" and "Table 3" each of which clearly identify the need for a <u>pair</u> of quaternary ammonium compounds needed to provide a disinfecting benefit to Kitzke's aerosol compositions. However, the additional consideration of Kitzke with Tuominen

US Serial No. 10/645248 Page 16 of 17

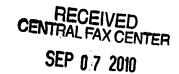
would not be technically feasible and would be considered inoperable as Tuominen's thickened AAC compositions would be recognized by a skilled artisan as being unsuitable for use in a pressurized, propellant containing composition which is an essential feature of Kitzke's compositions as such would be expected to clog any nozzle or dispenser due to the high viscosity of Tuominen's thickened AAC compositions. Such an inoperative combination would not render the applicant's presently claimed invention as being anticipated or being obvious and does not provide a suitable basis for maintaining the rejection of the claim. The Examiner is reminded that a reference may teach away from a use when that use would render the result inoperable. *McGinley v. Franklin Sports, Inc.*, 262 F.3d 1339, 1354 [60 USPQ2d 1001] (Fed. Cir. 2001). "A reference may be said to teach away when a person of ordinary skill, upon reading the reference, would be discouraged from following the path set out in the reference, or would be led in a direction divergent from the path that was taken by the applicant." *In re Gurley*, 27 F.3d 551, 553 [31 USPQ2d 1130] (Fed. Cir. 1994).

Further, the additional consideration of Kitzke also would require that the Tuominen thickened AAC composition would also necessarily require a pair of specific germicidally effective quaternary ammonium compounds, which are clearly indicated as being essential in Kitzke's compositions. The currently amended independent claims exclude germicidally effective quaternary ammonium compound as possible, albeit optional, constituents.

Accordingly, reconsideration of the propriety of the rejection under 35 USC 103(a) is requested, and withdrawal of the rejection is urged.

The early issuance of a Notice of Allowability is solicited.

US Serial No. 10/645248 Page 17 of 17



CONDITIONAL AUTHORIZATION FOR FEES

Should any further fee be required by the Commissioner in order to permit the timely entry of this paper, including any extension of time fees, the Commissioner is authorized to charge any such fee to Deposit Account No. 14-1263.

Respectfully Submitted;

Andrew N. Parfomak, Esq. Date:

Reg.No. 32,431

Norris, McLaughlin & Marcus, PC

875 Third Ave., 18th Floor New York, NY 10022

Tel: 212 808-0700

CERTIFICATE OF TELEFAX TRANSMISSION UNDER 37 CFR 1.8

I certify that this document, and any attachments thereto, addressed to the: "Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450" is being telefax transmitted to (571) 273-8300 at the United States Patent and Trademark Office.

Allyson Ross

Date:

C:\ANPCMB\102792\158\Amendment11.doc